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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,914	01/28/2005	Richard D. Gresham	2857 (203-3424)	6921
Covidien 60 Middletown Avenue North Haven, CT 06473			EXAMINER MCEVOY, THOMAS M	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 06/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,914

Applicant(s)

GRESHAM, RICHARD D.

Examiner

THOMAS MCEVOY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Applicant's amendment filed on March 10th 2008 has overcome the previous claim objections of record.
2. Claim 10 is objected to because the term "an the second sleeve" should read "and the second sleeve". Claim 21 is objected to because the term "being being" should read "being". Claim 25 is objected to because the word "clost" should read "close". Claim 30 is objected to because the term "an cover" should read "a cover". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Applicant's amendment filed on March 10th 2008 has overcome the previous 35 USC 112 rejections of record.
4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-3 and 5-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the tool assembly" in lines 7, 8 and 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3 and 5-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bulow et al. (US 5,665,073).

Regarding claims 1-3 and 13, Bulow et al. disclose a surgical instrument comprising: a body portion, 32/36, 42/46, and/or 52/56; a tool member, 38, 48 and/or 58, supported on the distal end of the body portion; and a liquid impermeable elongated cover 12 (col. 5, lines 30-31) supported about the body portion of the instrument, the elongated cover being formed from a collapsible material and having a substantially tubular configuration having open proximal and distal ends, the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly, wherein when the elongated cover is in the first position the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position (the cover can be draped and secured via 11 at any position along the surgical instrument). Regarding claims 5-8 the cover deployment sleeve half-sections 72/73 are movable to move the cover from the first position to the second position while being urged together by o-ring 11 or cover 12.

Regarding claim 9, the sleeve includes a proximally located annular ring 76/77 dimensioned to facilitate movement of the sleeve between the retracted and advanced positions. Regarding claim 10, the first sleeve half-section includes at least one projection, 78 or 79 (Figure 3), and the second sleeve half-section includes at least one slot (the curved interior of 72 or 73). The projection can slide into the slot to maintain alignment between the first and second half-sections when the half-sections move outwardly (slide longitudinally relative to each other when stacked) with respect to each other. Regarding claim 11, movement of the cover deployment device from a retracted position to an advanced position can be used to invert the cover over the tool member. Regarding claim 12, the cover deployment device includes a distal engagement member 78/79, a proximal guide portion 76/77 and a central body portion 74/75 interconnecting the engagement member and the guide portion. Regarding claims 14-16, a closure drawstring, 18 or 19, can close the proximal end of the cover after it has moved over the tool member. Regarding claim 17 the distal end of the cover is removably fastened to the surgical instrument by 11.

8. Claims 21, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Jespersen (US 2003/0139767).

Regarding claim 21, Jespersen discloses a method of performing a surgical procedure comprising the following steps: providing a surgical instrument including a body portion 31, a tool member 34/36 and a cover 12, a distal end of the cover being secured about the instrument adjacent the tool assembly such that the cover is movable from a first position wherein the tool assembly is uncovered (Figure 5A) to a second

position wherein the tool member is at least partially covered (as in Figure 7; paragraph 0044); positioning the surgical instrument adjacent a surgical site and performing a surgical operation on desired tissue (Figure 5A); moving the cover from the first position to the second position by inverting the cover at least partially over the tool assembly; (as in Figure 7; paragraph 0044) and subsequently removing the surgical instrument from the surgical site (paragraph 0041). Regarding claims 25 and 26, the surgical instrument includes a closure drawstring 52, and the method further includes the step of actuating the closure drawstring to close the cover at a location distally of the tool member (paragraph 0042).

9. Claims 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 5,318,221).

Regarding claims 27, 28 and 30, Green et al. disclose a surgical instrument comprising: an elongated body portion 129; a tool assembly 134/136 supported on a distal end of the elongated body portion, the tool assembly including an anvil assembly and a shell assembly (Figure 15A), the shell assembly having a plurality of surgical staples (Figure 12); an elongated cover 127 having a distal end fastened about the elongated body portion at a location adjacent a proximal end of the tool assembly (Figure 15A). A cover deployment device 126 (or portion of 127 not covering tool assembly) is movably positioned about the elongated body portion (Figure 15), the cover deployment device extending along a portion of the length of the elongated body portion between the elongated body portion and the elongated cover (Figures 5A and 7, where 127 encloses 129 as shown with 124 in Figure 5A). Regarding claim 29, a

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diameter of the cover is substantially the same as the diameter of the cover deployment device (Figure 7).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulow et al. (US 5,665,073) in view of Williamson et al. (US 6,024,741).

13. Regarding claims 18-20, Bulow et al. disclose the device as disclosed above, and further disclose that the device is intended to protect the conduits of multiple surgical instruments (col. 5, lines 55-59), but do not disclose that it is usable with a linear/circular stapler or ultrasonic dissector. Williamson et al. disclose an ultrasonic cutter (col. 2, lines 1-11) circular/linear stapler (col. 3, lines 22-39) which has conduits, 30 or 19a-d. It would be obvious to one of ordinary skill in the art to combine the device

of Bulow et al. with the instrument of Williamson et al. in order to protect and maintain the sterility of the conduits.

14. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jespersen (US 2003/0139767) in view of Williamson et al. (US 6,024,741).

Regarding claims 22-24, Jespersen discloses the device as described above which is intended to be used with a grasping instrument but fails to disclose that the grasping instrument is a stapler or ultrasonic dissector. Williamson et al. disclose an ultrasonic cutter (col. 2, lines 1-11) and circular/linear stapler (col. 3, lines 22-39) and grasper (grasping elements 32 and 34). It would be obvious to one of ordinary skill in the art to combine the device of Jespersen with the instrument of Williamson et al. in order to contain and remove grasped/cut tissue.

Response to Arguments

15. Applicant's arguments with respect to claims 1-3 and 5-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. For example, Mizusawa (US 3,894,706) discloses a device with two half-sections for maintaining conduit or tubing in parallel alignment where one half-section contains a projection which is slidable into a slot of the other half-section for locking the sections together. Slais et al. (US 6,318,765) disclose a device with two half-sections which are interconnected by a projection and slot. The device is also intended for securing conduit or tubing.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731